

SAFETY DATA SHEET

Product name:	ProphyCare	Page:	1/12
Revision:	2021-04-12	Print date:	2022-07-12
Product No.:		SDS-ID:	EU-EN/2.0

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product name: ProphyCare

Article number:
741111 (ProphyCare PRO)
690125 (ProphyCare PRO, single dose)
731113 (ProphyCare Blue 250 96g/60ml)
731114 (ProphyCare Green 170 97g/60ml)
731112 (ProphyCare Red 120 84g/60ml)
731111 (ProphyCare Yellow 40 84g/60ml)
690123 (ProphyCare Blue 250 single dose 2g)
690122 (ProphyCare Green 170 single dose 2g)
690121 (ProphyCare Red 120 single dose 2g)
690120 (ProphyCare Yellow 40 single dose 2g)
690119 (ProphyCare mix single dose 2g)

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified use(s): ProphyCare PRO:
Paste for removal of coatings on teeth.

ProphyCare:
Paste for polishing teeth. Medical device. Directly invasive.

1.3. Details of the supplier of the safety data sheet

Supplier: Directa AB
P.O. Box 723
SE-194 27 Upplands Väsby
Tel:+46 850650575
Fax:+46 85903060
info@directadental.com

1.4. Emergency telephone number

Emergency telephone: National Poison Control Centres are available in Member Countries. or +46 (0)8-33 12 31 (Only during office hours)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

CLP: The product is not classified.
The product is considered as a medical device and contains a substance that has an occupational exposure limit. Therefore a safety data sheet must be provided on request.

2.2. Label elements

The substance/mixture does not meet the criteria for classification and labelling.

2.3. Other hazards

PBT/vPvB: Not Classified as PBT/vPvB by current EU criteria.

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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2. Mixtures

CLP:

<u>%:</u>	<u>CAS-No.:</u>	<u>EC No.:</u>	<u>REACH Reg. No:</u>	<u>Chemical name:</u>	<u>Hazard classification:</u>	<u>Notes:</u>
<0,3	7681-49-4	231-667-8	01-2119539420-47-xxxx	Sodium fluoride	Acute Tox. 3;H301 Eye Irrit. 2;H319 Skin Irrit. 2;H315 EUH032	
0.1-5	-	643-044-1	01-2119489379-17-xxxx	Titanium dioxide	-	

Notes:

Content of pigments in each product (applies to ProphyCare)

CCS ProphyCare Blue 250:

Chemical name: Acid Blue 9 (CI 42090, E133)

Content: 0,01-0,09 %

CAS-no.: 3844-45-9

EC-no.: 223-339-8

CCS ProphyCare Green 170:

Chemical name: Acid Blue 9 (CI 42090, E133)

Content: 0,01-0,09 %

CAS-no.: 3844-45-9

EC-no.: 223-339-8

Chemical name: Acid Yellow 23 (CI 19140, E133)

Content: 0,01-0,09 %

CAS-no.: 1934-21-0

EC-no.: 217-699-5

CCS ProphyCare Red 120:

Chemical name: Acid Red 51 (CI 45430, E133)

Content: 0,01-0,09 %

CAS-no.: 16423-68-0

EC-no.: 240-474-8

CCS ProphyCare Yellow 40:

Chemical name: Acid Yellow 23 (CI 19140, E133)

Content: 0,01-0,09 %

CAS-no.: 1934-21-0

EC-no.: 217-699-5

References: The full text for all hazard statements is displayed in section 16.

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SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation: Not relevant.

Skin contact: Flush skin thoroughly with water.

Eye contact: Immediately flush with plenty of water for at least 15 minutes. Remove any contact lenses and open eyelids widely. If irritation persists: Seek medical attention and bring along these instructions.

Ingestion: Rinse mouth with water. Contact physician if larger quantity has been consumed.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects: Repeated exposure may cause skin dryness or cracking. Splashes in the eyes may cause redness and irritation. May cause irritation to the mouth and throat.

4.3. Indication of any immediate medical attention and special treatment needed

Medical attention/treatments: Treat symptomatically. Contact physician if irritation persists.

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media

Extinguishing media: This product is not flammable. Use fire-extinguishing media appropriate for surrounding materials.

5.2. Special hazards arising from the substance or mixture

Specific hazards: During fire, gases hazardous to health may be formed.

5.3. Advice for firefighters

Protective equipment for fire-fighters: Selection of respiratory protection for fire fighting: follow the general fire precautions indicated in the workplace.

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SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions: Follow precautions for safe handling described in this safety data sheet.

Protective equipment: For protection, see section 7 and 8.

6.2. Environmental precautions

Environmental precautions: Avoid discharge into water courses or onto the ground. Inform Authorities if large amounts are involved.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up: Small spillages: Collect spillage with a moist cloth.
Large Spillages: Absorb spilled substance with sand or earth.

6.4. Reference to other sections

References: For emergency telephone number, see section 1
For personal protection, see section 8.
For waste disposal, see section 13.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Safe handling advice: Avoid contact with eyes and prolonged skin contact. Observe good chemical hygiene practices. Ventilate well. Wash hands before breaks and before smoking, eating or drinking.

Technical measures: Keep the workplace clean.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures for safe storage: No special precautions.

Storage conditions: Store at moderate temperatures in dry, well ventilated area. Store frostfree in closed original container. Storage time: 3 years.

7.3. Specific end use(s)

Specific use(s): The product is used for tooth polishing.

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Please note that there may be national occupational exposure limits.

8.2. Exposure controls

<u>Engineering measures:</u>	Observe occupational exposure limits and minimise the risk of inhalation of vapours.
<u>Personal protection:</u>	Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.
<u>Respiratory equipment:</u>	Under normal conditions of use respiration protection should not be required. In case of inadequate ventilation use suitable respirator.
<u>Hand protection:</u>	Risk of contact: Wear protective gloves. Use gloves of type nitrile or butyl rubber or 4H tested according to EN 374-3. The most suitable glove must be chosen in collaboration with the supplier of gloves, who can inform about the breakthrough time of the glove material.
<u>Eye protection:</u>	Risk of splashes: Wear approved safety goggles.
<u>Skin protection:</u>	Wear appropriate clothing to prevent repeated or prolonged skin contact.
<u>Hygiene measures:</u>	Wash hands after handling. Wash contaminated clothing before reuse.

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

<u>Physical state:</u>	Paste.
<u>Colour:</u>	Various colours: Purple. Blue. Green. Yellow Red.
<u>Odour:</u>	Mint
<u>Odour threshold:</u>	Not available.
<u>pH:</u>	5,0-6,0
<u>Melting point / freezing point:</u>	Not available.
<u>Boiling point:</u>	Not available.
<u>Flash point:</u>	Not available.
<u>Evaporation rate:</u>	Not available.
<u>Flammability (solid, gas):</u>	Not available.
<u>Explosion limits:</u>	Not available.
<u>Vapour pressure:</u>	Not available.
<u>Vapour density:</u>	Not available.
<u>Relative density:</u>	Not available.
<u>Solubility:</u>	Suspension.
<u>Partition coefficient (n-octanol/water):</u>	Not available.
<u>Auto-ignition temperature (°C):</u>	Not available.
<u>Decomposition temperature (°C):</u>	Not available.
<u>Viscosity:</u>	Not available.
<u>Explosive properties:</u>	Non-explosive
<u>Oxidising properties:</u>	Non-oxidizing

9.2. Other information

<u>Other data:</u>	Not available.
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SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity: Not reactive.

10.2. Chemical stability

Stability: Stable under normal temperature conditions.

10.3. Possibility of hazardous reactions

Hazardous Reactions: Contact with acid liberates very toxic gas.

10.4. Conditions to avoid

Conditions/materials to avoid: Extremes of temperatures. (>25°C - <0°C)

10.5. Incompatible materials

Incompatible materials: Acids.

10.6. Hazardous decomposition products

Hazardous decomposition products: None under normal conditions. When heating the product irritating vapours may be formed.

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SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute Toxicity (Oral): Based on available data, the classification criteria are not met.

Acute Toxicity (Dermal): Based on available data, the classification criteria are not met.

Acute Toxicity (Inhalation): Based on available data, the classification criteria are not met.

Skin Corrosion/Irritation: Based on available data, the classification criteria are not met.

Serious eye damage/irritation: Based on available data, the classification criteria are not met.

Respiratory or skin sensitisation: Based on available data, the classification criteria are not met.

Germ cell mutagenicity: Based on available data, the classification criteria are not met.

Carcinogenicity: Based on available data, the classification criteria are not met.

Reproductive Toxicity: Based on available data, the classification criteria are not met.

STOT - Single exposure: Based on available data, the classification criteria are not met.

STOT - Repeated exposure: Based on available data, the classification criteria are not met.

Aspiration hazard: Based on available data, the classification criteria are not met.

Inhalation: Not relevant at normal room temperatures. When heated, irritating vapours may be formed.

Skin contact: Prolonged contact may cause redness and irritation.

Eye contact: May irritate and cause redness and pain.

Ingestion: May cause irritation to the mouth and throat. Ingestion of large amounts may cause abdominal pain.

Specific effects: May cause sensitisation by skin contact.

Toxicological data: LD50 (oral, rat):
Sodium fluoride: 52 mg/kg

11.2. Information on other hazards

Endocrine disrupting properties: The product does not contain any substance identified as having endocrine disrupting properties.

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SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecotoxicity: Not classified as dangerous to the environment.

Sodium fluoride:
LC50 (Fish: *Onchorhynchus mykiss*)/96 hours: 51 mg/l
EC50 (*Daphnia magna*, 48 hours): 338 mg/l

12.2. Persistence and degradability

Degradability: The product consists mainly of inorganic compounds, which are not biodegradable.

12.3. Bioaccumulative potential

Bioaccumulative potential: Will not bio-accumulate.

12.4. Mobility in soil

Mobility: The product is mobile in soil. The product is soluble in water.

12.5. Results of PBT and vPvB assessment

PBT/vPvB: This product does not contain any PBT or vPvB substances.

12.6. Endocrine disrupting properties

Endocrine disrupting properties: The product does not contain any substance identified as having endocrine disrupting properties.

12.7. Other adverse effects

Other adverse effects: None known.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Dispose of waste and residues in accordance with local authority requirements.

Waste from residues: EWC-code: 18 01 07

Empty packaging: The packaging should be collected for reuse.

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SECTION 14: TRANSPORT INFORMATION

The product is not covered by international regulation on the transport of dangerous goods (IMDG, IATA, ADR/AND/RID).

14.1. UN number

UN-No: -

14.2. UN proper shipping name

Proper Shipping Name: -

14.3. Transport hazard class(es)

Class: -

14.4. Packing group

PG: -

14.5. Environmental hazards

Marine pollutant: -

Environmentally Hazardous substance: --

14.6. Special precautions for user

Special precautions: Not relevant.

14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code

Transport in bulk: Not relevant.

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SECTION 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

National regulation: Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, with amendments.

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 with amendments.

Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work, with amendments.

Commission Directive 2000/39/EC of 8 June 2000 establishing a first list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work, with amendments.

Commission Directive 91/322/EEC of 29 May 1991 on establishing indicative limit values by implementing Council Directive 80/1107/EEC on the protection of workers from the risks related to exposure to chemical, physical and biological agents at work, with amendments.

Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work, with amendments.

Directive 2009/148/EC of the European Parliament and of the Council of 30 November 2009 on the protection of workers from the risks related to exposure to asbestos at work, with amendments.

Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents, with amendments.

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives, with amendments.

2014/955/EC: Commission Decision of 18 December 2014 amending Decision 2000/532/EC as regards the list of wastes.

15.2. Chemical Safety Assessment

CSA status: No chemical safety assessment has been carried out.

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SECTION 16: OTHER INFORMATION

The user must be instructed in the proper work procedure and be familiar with the contents of these instructions.

The following sections contain revisions or new statements: 1, 3, 16.

Abbreviations and acronyms used in the safety data sheet: CSA = Chemical Safety Assessment.
EC50 = Effective Concentration 50%.
LC50 = Lethal Concentration 50%.
LD50 = Lethal Dose 50%.
PBT = Persistent, Bioaccumulative and Toxic.
vPvB = very Persistent and very Bioaccumulative.

Wording of H-statements:

H301	Toxic if swallowed.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
EUH032	Contact with acid liberates very toxic gas.

The information on this data sheet represents our current data and is reliable provided that the product is used under the prescribed conditions and in accordance with the application specified on the packaging and/or in the technical guidance literature. Any other use of the product which involves using the product in combination with any other product or any other process is the responsibility of the user.

Made by DHI - Environment and Toxicology, Agern Allé 5, DK-2970 Hørsholm, Denmark.
www.dhigroup.com.
